

ANDERSON EXHIBIT 6E

Calculation of Rebate Amount Due to Each State For Innovator Drugs

123. Under the Rebate Program, 42 U.S.C. §1396r-8(c)(1)(A) and (B), each State's basic rebate amount for each quarterly (three month) rebate period, for each dosage form and strength of a single source drug or innovator multiple source drug (collectively, the "innovator drugs"), has been equal to the product of:

a. The total number of units of each dosage form and strength paid for under the State Medicaid drug reimbursement plan in the rebate period (as reported by the State); and

b. the greater of

- (i) the difference between the "Average Manufacturer Price" ("AMP") minus the manufacturer's "Best Price" ("BP") for the dosage form and strength of the drug or
- (ii) the minimum rebate percentage of the AMP (the minimum rebate percentage has been 15.1% since January 1, 1996.¹)

124. Pursuant to 42 U.S.C. §1396r-8(c)(1)(C), BP is defined as the following:

¹ Prior to that date, the minimum rebate percentage was as follows:

- (i) 12.5 percent after December 31, 1990, and before October 1, 1992;
- (ii) 15.7 percent after September 30, 1992, and before January 1, 1994;
- (iii) 15.4 percent after December 31, 1993, and before January 1, 1995;
- (iv) 15.2 percent after December 31, 1994, and before January 1, 1996.

Temporary limitation on maximum rebate amount - -

- (i) prior to January 1, 1992, (b) of this paragraph could not exceed 25 percent of the AMP,
- (ii) After December 31, 1991, and before January 1, 1993, (b) of this paragraph could not exceed 50 percent of the AMP.

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- (i) The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States, excluding - -
 - (I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B);
 - (II) any prices charged under the Federal Supply Schedule of the General Services Administration;
 - (III) any prices used under a State pharmaceutical assistance program; and
 - (IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.
- (ii) Special rules. The term "best price" - -
 - (I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

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- (II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and
- (III) shall not take into account prices that are merely nominal in amount.

125. Best Price Exclusion - Nominal Price. A “nominal price,” or a price that is “merely nominal in amount,” is “a price that is less than 10 percent of AMP.” See Medicaid Program: Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers, 60 Fed. Reg. 48442 (Sept. 19, 1995) (hereinafter “60 Fed. Reg. 48442”); see also the rebate agreement entered into between Secretary of the Department of Health and Human Services and drug manufacturers participating in the Medicaid Rebate Program (the “Rebate Agreement”). The statute expressly excludes nominal prices from the calculation of Best Price.

AMP Calculation

126. Pursuant to 42 U.S.C. §1396r-8(k)(1), AMP means, during the rebate period, “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.”

127. For each dosage form and strength of an innovator drug, drug manufacturers must also pay an additional rebate based upon the amount, if any, by which the drug’s AMP

has risen (for the calendar quarter beginning with the latter of either July 1, 1990 or the time the drug was first marketed) more quickly than the rate of inflation as determined by reference to the national Consumer Price Index for urban consumers ("CPIU"). 42 U.S.C. §1396r-8(c)(2)(A).

Calculation of Rebate Amount Due to Each State For Non-Innovator Drugs

128. The Medicaid Rebate Statute provides that each State's basic rebate for all other prescription (non-innovator) drugs has been equal to the product of:

(A) In general:

1. the applicable percentage (as described in subparagraph (B)) of the AMP for the dosage form and strength for the rebate period, and
2. the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State Medicaid drug reimbursement plan for the rebate period.

(B) "Applicable percentage" defined

For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning -

- (i) before January 1, 1994, is 10 percent, and
- (ii) after December 31, 1993, is 11 percent.

42 U.S.C. §1396r-8(c)(3)(A) and (B).

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DEFENDANTS Report AMP and BP to CMS to Calculate the Medicaid Rebate

129. Manufacturers report their AMPs and BPs to CMS on a quarterly basis. CMS, in turn, calculates the rebate amount as either AMP minus BP (or uses the current 15.1% minimum) for innovator drugs, or AMP multiplied by 11% (or 10% prior to 1994) for non-innovator drugs, and compares the CPIU to any rise in the AMP of each innovator drug. CMS then forwards the resulting rebate amounts by NDC number (the identification number for each dosage and unit size for each drug), to each State. Each State then multiplies the rebate amount for each NDC number by the number of units of that drug that the State paid for during the quarter to determine the rebate amount due and submits this amount to the manufacturer for payment. The manufacturer remits its payment to the state on a quarterly basis, withholding any disputed amount.

**SECTION NO. 9
THE FALSE CLAIMS SCHEMES**

**A. DEFENDANTS' SCHEMES RESULTED IN MULTIPLE
VIOLATIONS OF THE FALSE CLAIMS ACT**

130. By knowingly reporting falsely inflated cost and price representations bearing no reasonable relation to the prices generally and currently paid by Providers in the marketplace for the specified drugs, both directly to Medicare/Medicaid and indirectly by means of the various drug price and cost publishing compendia, the DEFENDANTS caused Providers to submit false claims for excessive reimbursement to Medicare/Medicaid.

Pursuant to this kickback scheme engineered by DEFENDANTS, Providers then received a windfall financial benefit from Medicare/ Medicaid in the amount by which the Government's approved "reimbursement" amount exceeded a reasonable estimate of acquisition costs generally and currently available to Providers in the marketplace. Each DEFENDANT is liable, therefore, for damages to Medicare/Medicaid and other governmental health care programs under the False Claims Act, 31 U.S.C. §§3729-3732.

131. Each DEFENDANT acted knowingly, as that term is defined in the False Claims Act, in providing the false and misleading price and cost information and in marketing the inflated Spread, which actions caused Medicare/Medicaid to pay claims for the DEFENDANTS' drugs in excessive amounts.

132. Liability For Damages To Medicaid And Medicare As To Specified Medicare/Medicaid Drugs --

a. As the DEFENDANTS knew, when Providers purchased a drug for which the reported prices and costs were falsely inflated, not only would Providers receive excessive reimbursement under Medicaid for such drug but, in all likelihood, the Provider would receive excessive reimbursement under Medicare as well. Also as DEFENDANTS knew, this was true even in the case of multiple-source Medicare drugs because in addition to DEFENDANTS' own inflated reported AWP's, other drug manufacturers were falsely inflating their AWP's for competing versions of such drugs falling under the same HCPCS code. The DEFENDANTS were aware of the amount of excessive reimbursement which a Provider would receive under Medicare and Medicaid for their specified drugs.

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b. DEFENDANTS inflated their reported price and cost information and marketed the inflated Spread resulting therefrom, to increase the sales of their respective specified drugs to Providers. As a result, they caused false claims for excessive reimbursement to be made to both the Medicare and Medicaid Programs. But for each DEFENDANT'S actions, Medicaid/Medicare would not have paid the excessive reimbursement amounts that were in fact paid for each DEFENDANT'S respective specified drugs. Each DEFENDANT is thus liable under the False Claims Act for each Medicare and Medicaid reimbursement claim for its respective specified drugs which resulted in payment of a falsely inflated reimbursement amount.

133. Medicaid Drugs and Single Source Medicare Drugs -- As the DEFENDANTS knew, for any given drug covered by Medicaid, only the reported price or cost of that specific drug was utilized to calculate the reimbursement amount, and not the reported price or cost of any competing brand or generic version of the same drug with a different NDC number. As the DEFENDANTS also knew, for any single source drug covered by Medicare, only that drug's reported AWP was utilized to calculate the Medicare reimbursement amount since no competing brand or generic version sharing the same HCPCS code existed.

134. Joint And Several Liability As To Multiple-Source Drugs Under Medicare --

a. Each DEFENDANT which reported a falsely inflated AWP for its brand or generic version of a drug falling under a given HCPCS code is jointly and severally liable with every other DEFENDANT that reported a falsely inflated AWP for its version of the drug falling under that HCPCS code, for the sum of all falsely inflated reimbursement amounts

paid to Providers under that HCPCS code. In particular: 1) each DEFENDANT knowingly engaged in the same wrongful conduct, namely, reporting an inflated AWP; 2) each DEFENDANT acted concurrently and in concert with other drug manufacturers in reporting falsely inflated AWPs; 3) each DEFENDANT knew that other drug manufacturers were inflating their AWPs on their respective version of the drug; 4) it was foreseeable by each DEFENDANT that their wrongful conduct (reporting an inflated AWP) could, if combined with the same wrongful conduct on the part of another drug manufacturer(s), jointly cause an inflated reimbursement amount to be paid to Providers for the drug; 5) the DEFENDANTS' wrongful conduct did in fact combine to jointly cause the payment of an inflated reimbursement amount for the drug; and 6) in each instance the harm resulting from DEFENDANTS' similar conduct in reporting inflated AWP's was inflicted upon the same entity, namely, the Federal Government.

b. DEFENDANTS knew the applicable drug reimbursement formula for multiple-source drugs and knew, if not specifically, at least approximately, the amount of reimbursement a Provider would receive under Medicare for their specified drugs. The DEFENDANTS also knew that other drug manufacturers were inflating their reported AWPs for such specified drugs and thus knowingly participated jointly in a scheme that caused Providers to receive excessive reimbursements for such specified drugs under Medicare. The DEFENDANTS had no legitimate business purpose for inflating the reported AWP's of their specified drugs. In fact, the DEFENDANTS engaged in that practice only to illegally inflate the drug reimbursement amounts calculated and paid by both Medicare and the

State Medicaid Programs, in order to increase sales of their respective specified drugs at the expense of those governmental programs. With respect to each specified drug which was a multiple-source drug reimbursed under Medicare, DEFENDANTS that: 1) were sources of any brand or generic version of such drug falling under a given HCPCS code, and 2) knowingly reported inflated AWP information with respect to their versions of such drug, were therefore jointly and severally liable for the sum of the falsely inflated reimbursement amounts paid to Providers for all brand and generic versions of that multiple-source drug.

135. Joint And Several Liability As To Multiple-Source Drugs Under Medicaid—

a. Many State Medicaid programs reimburse certain Providers, such as physicians, for multiple-source drugs by using a methodology similar to the J Code Medicare reimbursement methodology previously described herein. To the extent that any DEFENDANT jointly with other drug manufacturer(s) caused inflated reimbursement amounts to be paid for any multiple-source drug under any such State Medicaid reimbursement methodology, each such DEFENDANT is jointly and severally liable for the total of the falsely inflated reimbursement amounts paid for all versions of such multi-source drug for the reasons set forth in the preceding paragraph.

b. Some of the specified drugs are multiple-source drugs which are subject to a Federal Upper Limit ("FUL") for Medicaid purposes. Those drugs subject to an FUL are oral drugs dispensed and billed to Medicaid by pharmacies (drugs dispensed in connection with physician services claims are not subject to an FUL). Pursuant to the FUL

limits, the reimbursement amount for such drugs has been capped at 150 percent of the reported price for the least costly therapeutically equivalent version of the drug plus a reasonable dispensing fee. 42 CFR §447.331-333. Each DEFENDANT who manufactured a drug subject to an FUL and reported a falsely inflated price or cost with respect to such drug is, therefore, jointly and severally liable (along with all other DEFENDANTS who engaged in the same wrongful conduct with respect to such drug) for the sum of all falsely inflated reimbursements paid for all versions of that drug. In this regard, each such DEFENDANT: a) knowingly reported falsely inflated price and cost information with respect to such drug, b) knew the reimbursement methodology for an FUL drug, and c) knew that if it provided prices and costs generally and currently available in the marketplace, the reimbursement amount would not have been inflated beyond what the FUL was intended to allow. Each such DEFENDANT also knew that if the DEFENDANT reported an inflated price or cost for its version of the drug, it was foreseeable that the reimbursement amount, despite the FUL, would be excessive, particularly since the DEFENDANT knew, or had ample reason to believe, that other drug manufacturers were falsely inflating their reported prices and/or costs for their respective versions of such multiple-source drug.

136. Joint And Several Liability Arising From Drug Marketing Agreements – At various times certain DEFENDANTS entered into contractual relationships (“Drug Marketing Agreements”), with other drug companies to either: a) market and sell a drug which the other drug company manufactured or b) allow another drug company to market and sell a drug the DEFENDANT manufactured. When Providers sought Medicare/Medicaid

reimbursement for drugs subject to such a marketing agreement, the reimbursement amount typically was calculated with reference to the prices and costs reported by the manufacturer. When these reported prices and costs were falsely inflated, therefore, both the drug company with marketing rights and the drug manufacturer, enjoyed the benefit of the resulting inflated reimbursement amounts through increased sales. Drug companies with marketing rights knew that drug manufacturers had falsely inflated the reported prices and costs of the drugs covered by Drug Marketing Agreements. In essence then, when manufacturers of drugs subject to Drug Marketing Agreements reported falsely inflated prices and costs of those drugs, both the manufacturers and the marketers were knowingly participating jointly in a scheme that enabled Providers to receive excessive Medicare/Medicaid reimbursement for such drugs. Therefore, to the extent certain DEFENDANTS entered into such Drug Marketing Agreements to either grant or to receive marketing and selling rights to drugs for which prices and costs were falsely inflated, they are each jointly and severally liable with the other party to such Agreement for the sum of the falsely inflated reimbursement amounts paid to Providers for such drugs.

137. The DEFENDANTS knew that Medicare/Medicaid would not pay or approve claims for the specified drugs if it were disclosed to Medicare/Medicaid that said claims were for amounts that included kickbacks.

138. The DEFENDANTS also knew that the Providers, in presenting claims for the specified drugs to Medicare/Medicaid, would not and did not disclose that the claim amounts included kickbacks.

139. Each of the DEFENDANTS carried out its scheme to defraud Medicare/Medicaid by knowingly providing false and misleading price information directly or indirectly to Medicare/Medicaid so that Providers would be reimbursed in excessive amounts for its drugs. The DEFENDANTS thus each participated in a fraudulent scheme to cause Medicare/Medicaid to pay and approve false claims in excessive amounts.

140. Each of the claims in question is a false claim under the False Claims Act, in part, because each was supported by, and the reimbursement amount was determined from, the false and misleading price information provided by the DEFENDANTS in connection with their respective specified drugs.

141. The false claims at issue in this action are all claims for reimbursement submitted to Medicare/Medicaid by or on behalf of Providers that sought and received payments in excessive amounts because of false and misleading price and cost representations made by the DEFENDANTS directly or indirectly to Medicare/Medicaid. The false claims at issue number in the tens of thousands, and were submitted by thousands of Providers nationwide throughout the relevant time period of the Complaint. Each claim is in the possession of Medicare or one of the applicable State Medicaid Programs.

142. For many of the Specified Drugs, the Relator has identified the false claims to the Federal government by providing prices generally and currently available in the marketplace that were concealed from Medicare/Medicaid by the DEFENDANTS for each specified drug; by providing specific identification information about the Specified Drugs;

and by providing the specific false price representations in question from which the Relator and the Federal government identified the specific false claims.

143. The damages sought herein include, but are not limited to, those arising from the false claims for the specified drugs set out in Sections 15 through 37 and elsewhere throughout this Third Amended Complaint. The damages sought herein also encompass all damages and penalties recoverable by reason of the false claim schemes of the DEFENDANTS alleged herein, relating to all drugs of all sizes, to the extent that the false price representations or records of DEFENDANTS were used in connection with, considered or made available in, caused, aided or otherwise affected the presentment, payment or approval of false claims. These claims also encompass recovery of the funds paid for false claims due to the DEFENDANTS' false drug price representations, regardless of the Federal or State program that actually expended the funds, the person or entity that ultimately received the funds, or the person or entity from which the Federal government or the States ultimately recovers the funds.

B. THE NATURE AND IMPACT OF THE DEFENDANTS' FALSE CLAIM SCHEMES

144. **DEFENDANTS Actively Used the Inflated Spread as a Marketing Tool Directed at Providers to Promote Increased Sales of the Specified Drugs.** By means of, among other things, inflated Spreads posted on Econolink and other wholesaler computer programs, direct mailing, facsimile transmission and verbal communications by sales representatives, DEFENDANTS repeatedly and systematically promoted the inflated

reimbursement amounts Providers would receive from both Medicare and Medicaid as a result of DEFENDANTS' inflated reported prices and costs.

145. **The Government Loses The Benefit Of Normal Price Competition.** The DEFENDANTS' scheme of creating and marketing inflated Spreads by reporting falsely inflated prices has also deprived the Government of the benefits of normal price competition, causing it in some cases to pay more than one thousand percent of the price that otherwise would be set by normal market forces. The following chart shows examples of especially exorbitant Spreads resulting from the DEFENDANTS scheme:

Defendant	Drug/Dosage	NDC #	AWP	Relator's Cost	AWP \$ Spread	AWP % Spread
Geneva	Cimetidine Tablets 400 mg	00781-1449-05	\$716.84	\$55.06	\$661.78	1,202%
Geneva	Haloperidol Tablets 10 mg	00781-1397-10	\$679.30	\$38.31	\$640.99	1,673%
Mylan	Doxazosin Tablets 1 mg	00378-4021-01	\$92.35	\$7.61	\$84.74	1,113%
Mylan	Meclofenamate Capsules 100 mg	00378-3000-01	\$356.70	\$16.31	\$340.39	2,087%
Schein	Atenolol Tablets 50 mg	00364-2513-90	\$75.99	\$5.52	\$70.47	1,277%
Schein	Ranitidine Tablets 150 mg	00364-2633-05	\$743.91	\$24.40	\$719.51	2,949%

146. **Reported Prices On Drugs Sometimes Rose While Prices In The Marketplace Stayed Constant Or Decreased.** The Government and its health program beneficiaries were damaged when the DEFENDANTS created a financial inducement for Providers to order drugs by increasing the Spread over time.

**SECTION NO. 10
THE DEFENDANT DRUG MANUFACTURERS'
KNOWLEDGE OF THE FALSE CLAIMS SCHEMES**

147. The DEFENDANTS were prohibited by the False Claims Act from causing the presentation of false claims for Government funds, were required by the Food and Drug Act to refrain from reporting misleading information about their drug products, and were prohibited by the Medicare and Medicaid Anti-Kickback laws from arranging financial inducements for Providers.

148. The patients and third party payers, including the Medicare and State Medicaid Programs, were not aware of the prices for the specified drugs generally and currently available in the marketplace to the physician, clinic or pharmacy presenting claims for reimbursement. The DEFENDANTS concealed from the Medicare and State Medicaid Programs price reductions occurring due to competition in the marketplace and falsely and fraudulently reported drug prices that far exceeded the prices generally and currently available in the marketplace.

149. At all times material to this action, each of the DEFENDANTS acted "knowingly" as that term is defined at 31 U.S.C. §3729(b):

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a. In causing false or fraudulent claims to be presented for payment or approval by the Medicare and State Medicaid programs; and

b. In making or using false statements or records to get false or fraudulent claims approved or paid by the Medicare and State Medicaid Programs.

150. The DEFENDANT DRUG MANUFACTURERS knew the following:

a. Each of the DEFENDANT DRUG MANUFACTURERS knew that Medicaid was required to pay claims based upon the Estimated Acquisition Cost ("EAC") of the drugs to the Provider submitting the claim. 42 C.F.R. §447.331.

b. Each of the DEFENDANT DRUG MANUFACTURERS knew that federal statutes and regulations limited reimbursement of Medicaid claims for the specified drugs to a reasonable estimation of the acquisition cost.

c. Each of the DEFENDANT DRUG MANUFACTURERS knew that neither Medicare nor Medicaid was authorized or permitted by applicable law to pay claims for the specified drugs in excessive amounts.

d. Each DEFENDANT DRUG MANUFACTURER knew that the State Medicaid Programs contracted through their fiscal agents with First Databank and Medi-Span to obtain the DEFENDANT's reported prices and costs and used the prices from First Databank and Medi-Span in estimating acquisition costs for the specified drugs for reimbursement purposes.

e. Each DEFENDANT knew that Medicare, through its Carriers and DMERCs, utilized DEFENDANTS' reported AWP prices as contained in Red Book, to establish its reimbursement amounts for the specified drugs.

f. Each of the DEFENDANT DRUG MANUFACTURERS knew that they were supplying to First DataBank, Red Book and Medi-Span, prices and costs which these price and cost publishing compendia reported to Medicare and/or Medicaid and that these compendia relied on DEFENDANTS to obtain the prices they reported.

g. Each of the DEFENDANTS knew highly detailed information about the sales of its specified drugs, required wholesalers to report sales information back to it, and wholesalers did in fact routinely report back to each of the DEFENDANTS, all prescription drug sales by NDC number, provider name and the actual price the Provider had paid.

h. Each of the DEFENDANTS knew, and in fact, closely monitored the prices, with and without discounts, that Providers as well as wholesalers were paying for DEFENDANTS' specified drugs. Such information was of utmost importance to DEFENDANTS in conducting their business affairs such as calculating and projecting revenue and profits, and making marketing, manufacturing and distribution decisions.

i. Each of the DEFENDANTS knew they were able to report price and cost information which fairly and reasonably represented market prices and had information readily available to it which would have enabled it to report price and cost information which fairly and reasonably represented sales in the marketplace.

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j. Each of the DEFENDANTS knew of the approximate size of the Spread for its specified drugs under both Medicare and Medicaid.

k. Each of the DEFENDANTS knew that prices it reported to First DataBank, Red Book and Medi-Span, or directly to a state Medicaid program, were false, and were vastly higher than the prices Providers were generally and currently paying for their specified drugs.

l. Each of the DEFENDANTS knew that the greater the Spread on a drug, the greater the inducement to a Provider to purchase that drug instead of a competing brand or generic drug.

m. Each of the DEFENDANTS systematically concealed from or otherwise failed to report to drug pricing and cost reporting compendia and state Medicaid programs, decreases in prices of the specified drugs to Providers.

n. Each of the DEFENDANT DRUG MANUFACTURERS knew that Federal and State statutes and regulations prohibited them from making misleading representations about the specified drugs, including misleading price or cost representations.

151. Each of the DEFENDANT DRUG MANUFACTURERS was required to comply with the Federal Food, Drug and Cosmetic Act 21 U.S.C. §321 et seq., and the regulations promulgated pursuant thereto.

152. The DEFENDANTS' price and cost representations about the specified drugs constituted advertising subject to the "labeling" provisions of the Federal Food and Drug Act and related regulations. 21 C.F.R. §202.1(l).

153. Each of the DEFENDANT DRUG MANUFACTURERS was prohibited from disseminating any information about the prices or costs of its specified drugs that was "false or misleading in any particular . . ." 21 U.S.C. §352.

154. Each of the DEFENDANT DRUG MANUFACTURERS had a duty to ensure that its representations about prices and costs of the specified drugs were not misleading, taking into account:

. . . not only representations made or suggested by statement, word, design, device, or any combination thereof, but also to the extent to which the labeling or advertising fails to reveal facts material in light of such representations.

21 U.S.C. §321(n).

155. The DEFENDANT DRUG MANUFACTURERS regularly made to State Medicaid Programs direct representations of false price and cost information that were utilized by those Programs in approving and paying Providers' reimbursement claims.

156. The DEFENDANT DRUG MANUFACTURERS knew and were fully capable of reporting the prices and costs of the specified drugs generally and currently available in the marketplace and did so when it was economically beneficial to them, a fact that further illustrates that they acted knowingly when reporting falsely inflated prices and costs to drug price publishing compendia and directly to state Medicaid programs.